EXHIBIT A

A randomized, double-blind, placebo-controlled, dose-escalation study of intravenous adult human mesenchymal stem cells (Prochymal™) following acute myocardial infarction

Joshua Hare, Jay Traverse, Timothy Henry, Nabil Dib, Robert Strumpf, Steven Schulman, Gary Gerstenblith, Anthony DeMaria, Ali Denktas, Roger Gammon, James Hermiller, Mark Reisman, Gary Schaer, Warren Sherman

Data was presented at the March 2007 American College of Cardiology conference

Protocol/Methods

Aims

This clinical trial was designed to:

- Test that allogeneic mesenchymal stem cells can be safely administered intravenously within 10 days of an acute myocardial infarction
- Provide provisional evidence to support subsequent efficacy studies

Major Inclusion Criteria

- Adults (male or female) from 21 to 85 yrs
- First myocardial infarction 1 to 10 days prior to randomization
- Patent infarct-related artery demonstrated by coronary angiography
- Ejection fraction between 30% and 60% (echocardiogram or ventriculogram)
- Hemodynamically stable for ≥ 24 hours prior to randomization
- Elevation of >2 times upper limit of normal of CK-MB or troponin during initial hospitalization for the index MI
- Karnofsky performance status score of ≥ 60

Rationale

Mesenchymal Stem Cells (MSCs)

- Traffic to injured tissues including myocardium
- Have potent anti-inflammatory properties
- Preclinical studies
  - Improved tissue perfusion
  - Endogenous cardiac repair
  - Reduce cellular apoptosis
  - Functional restoration and reduced infarct size
- Have demonstrated safety and efficacy in graft vs. host disease (GvHD), Crohn's disease, and orthopedic indications

Major Endpoints

- **Primary Endpoint**
  - Treatment emergent serious adverse events
- **Pre-specified Safety Measures**
  - Arrhythmia – Holter Monitoring
  - Pulmonary Function – PFTs
  - Ectopic tissue formation – CT
  - MACE
  - Overall functional performance – physician global assessment grading patients as improved, unchanged or worsened

Prochymal™ Trial Synopsis

- **Objectives** - To determine the safety and exploratory efficacy of 3 different dose levels of allogeneic bone marrow-derived MSCs (Prochymal™) compared to placebo in patients post acute MI
- **Trial Design:**
  - Randomized, double-blind, placebo-controlled
  - Dose-escalation following DSMB review after each dose cohort
- **Treatment:** Single infusion of investigational agent 3-10 days following MI
  - 0.5, 1.6, and 5 x 10^8 cells / Kg
- **Number of Subjects:**
  - 60 subjects in 4 cohorts were enrolled
  - 53 subjects were treated at 10 sites
- **Trial sponsored by Osiris Therapeutics, Inc.**

Baseline Conditions

All Randomly Assigned Population

	MSCs All Cohorts N=39	Placebo All Cohorts N=21
Age (years)	59.8 (12.1)	54.3 (10.1)
Sex		
Male	32 (82.1%)	17 (81.0%)
Female	7 (17.9%)	4 (19.0%)
BMI	29.8 (6.5)	30.3 (4.4)
Ant MI (%)	19 (48.7%)	12 (57.1%)
EF (%)	50.4 (10.6)	48.7 (9.6)
PVCs (24 hrs)	211 (827)	57 (156)
FEV1 (% pred)	74.0 (15.4)	76.7 (17.6)

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Results

Safety Results: Adverse Events

All Cohorts

	MSCs (N=34)	Placebo (N=19)	P-value Fisher's Exact Test
Total Number of Adverse Events (AEs)	181	132	
Average AEs per Patient	5.3	7.0	
Number of Subjects with at Least One AE	33 (97.1%)	19 (100.0%)	
Cardiac Disorders	15 (44.1%)	9 (47.4%)	>0.999
Gastrointestinal Disorders	9 (26.5%)	4 (21.1%)	0.749
General Disorders and Administration Site Conditions (chest pain, fatigue, etc.)	14 (41.2%)	13 (68.4%)	0.086
Immune System Disorders	2 (5.9%)*	0	0.531
Infections and Infestations	11 (32.4%)	5 (26.3%)	0.760

**The first immune system disorder in the MSC group involved an upper respiratory infection and the second involved seasonal allergies*

Drug related: None reported as probable

Key Safety Adverse Events

All Cohorts

	Prochymal™	Placebo	Total
Arrhythmias			
Total Number of AEs	7	12	19
Number of Subjects	34	19	53
Number of Subjects with at Least One AE	3 (8.8%)	7 (36.8%)	10 (18.9%)
Ventricular Tachycardia[1]	1	6	
Fishers's Exact Test P-Value			[1]0.025
Ectopic Tissue Formation (CT)			
Total Number of AEs	2[2]	1	3
Number of Subjects	34	19	53
Number of Subjects with at Least One AE	2 (5.9%)	1 (5.3%)	3 (5.7%)
Fishers's Exact Test P-Value			>0.999
De Novo Ectopic Tissue Formation	**0**	**1**	**1**

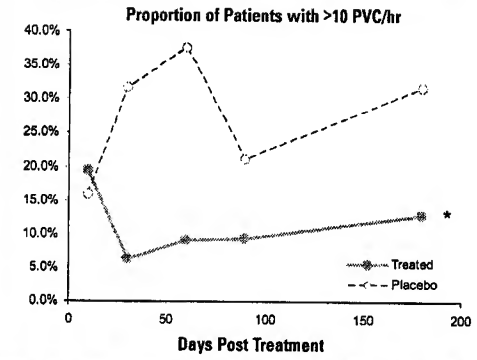
2 - Abnormalities were pre-existing at baseline

Rehospitalizations

All Cohorts

	MSCs	Placebo	Total
Total Number of Rehospitalizations	9	7	16
Average per Patient	0.26	0.37	
Number of Subjects Requiring at Least One Rehospitalization	8 (23.5%)	6 (31.6%)	14 (26.4%)
Average Time to Rehospitalization in Patients with Event	120 days	66 days	

Premature Ventricular Contractions



P<0.01 vs placebo

Dose response: Low dose not sustained

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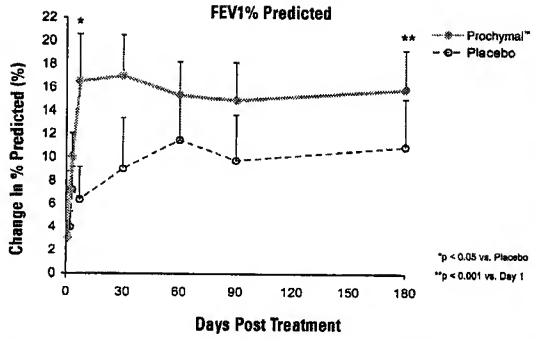
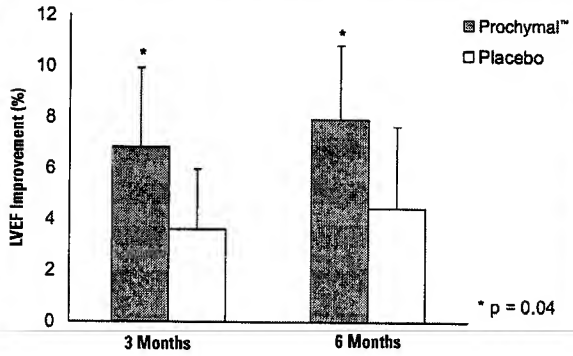
Results

Pulmonary Performance

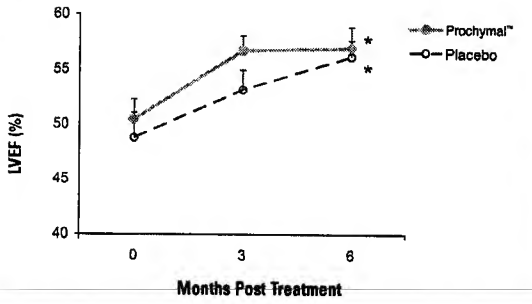


Effect observed in all dose cohorts

LV Ejection Fraction: Anterior MI's



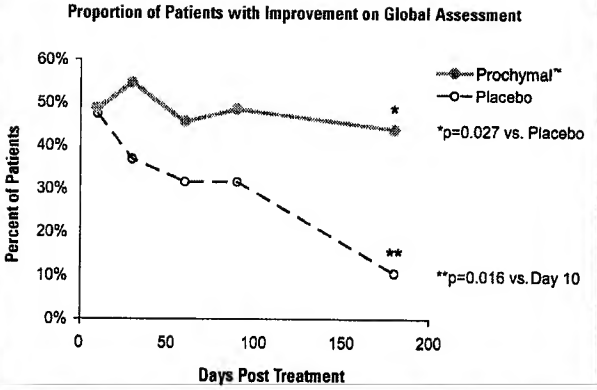
Left Ventricular Ejection Fraction



*P<0.05 for intra-group ANOVA

Dose response effect not observed

Global Assessment



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Summary/Conclusion

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- **This trial met its primary objective showing that IV administration of allogeneic MSCs is safe and well tolerated at all dose levels**
- **Specific safety monitoring revealed**
  - Reduction in arrhythmic AEs and PVCs on Holter Monitoring
  - No increase in ectopic tissue formation or events suggesting immunologic reactions
  - Improved pulmonary function
- **Exploratory efficacy**
  - Provisional evidence of improved EF, more evident in anterior MI group
  - Greater proportion of patients with improved global status
- **Dose ranging**
  - AE's were not dose related
  - PVC suppression – not sustained at low cell dose

Conclusions

- **The excellent safety profile of allogeneic MSCs supports ongoing studies of this cell-based therapeutic approach for structural heart disease**
- **The provisional findings from this phase I study are consistent with favorable effects of MSC administration on LV function, electrical stability, pulmonary function, and global health status in patients with acute myocardial infarction**
- **Further studies with larger numbers of subjects, powered to establish clinical benefits, are warranted**